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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,306	09/15/2000	Zhong Zhong	ORT1296	2391

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07/12/2002

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EXAMINER

CARLSON, KAREN C

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 07/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,306

Applicant(s)

ZHONG ET AL.

Examiner

Karen Cochran Carlson, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) 1-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 82-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Applicant's election with traverse of Invention 113, Claims 82-85, in Paper No. 7, filed May 2, 2002 is acknowledged. The traversal is on the ground(s) that the restriction should be an election of species and not an election of inventions. This is not found persuasive because each of the inventions are patentably distinct as set forth in the restriction requirement. Inclusion of several patentably distinct inventions in a single claim does not make them related as a genus-species.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-81 are withdrawn from further consideration by the Examiner because these Claims are drawn to non-elected inventions. Claims 82-85 are currently under examination.

Note to Applicants: The IDS filed January 29, 2001 (Paper 34) states that there are 3 sheets of references cited -see top wherein the statement "Sheet 1 of 3" is found. However, sheets 2 and 3 are not found in the application, and sheet 1 appears to list all of the submitted references.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The disclosure is objected to because of the following informalities: The text of Example 4 is not complete.

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 82-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 82-85 depend from non-elected inventions and are therefore indefinite because the elected invention of Claims 82-85 is not found within these claims.

In Claims 82 and 84, it is not clear what is intended by the term "discovered". Note that the methods of Claims 72 and 73 are not drawn to the discovery of a compound, but to the use of a compound to determine its effect on gene expression.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 82-85 are rejected under 35 U.S.C. 102(b) as being anticipated by Mazer et al. (USP 5,698,222; issued December 6, 1997). Mazer et al. teach a calcium supplement (Claims 82, 84) in a pharmaceutical formulation (Claims 83, 85).

Claims 82 and 84 ultimately depends from Claim 69. In Claim 69, a nucleic acid encodes a chimeric transcription factor comprising a constitutively active domain, a synthetic DNA binding domain, and a membrane anchoring domain, wherein the membrane anchoring domain comprises a protease cleave site. In Claims 72 and 73, the compound is stated to stimulate the activity of a protease to release the transcription factor from the membrane.

At page 17-18 of the specification, a fusion protein comprising of a strong transcription activator and a dominant membrane localization sequence comprising a protease cleavage site is cleaved by the protease calpain, which cleaves the fusion protein and releases the strong

transcriptional activator from the membrane to activate protein expression. Calpain activity is stated to be strictly dependent on calcium. Therefore, calcium is a compound that stimulates the activity of a protease to release a transcription factor from the membrane.

Additional art of record:

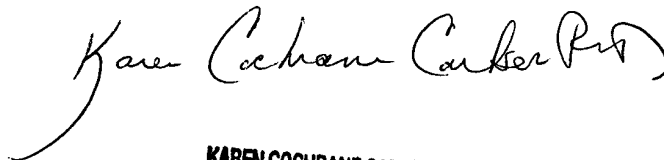
Protease activity is generally if not always dependent on calcium. The Examiner additionally cites Yamamoto et al. (USP 5,053,333; issued October 1, 1991) in which another protease is taught to be activated by calcium.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

July 11, 2002



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER